

### Remarks

Upon entry of the amendments, claims 1-11, 15, 25, 28-30, 39-47, 50-59, 64-69, 77-79, 82-83, 90, 97, 99, and 101 will be pending. Claims 12-14, 16-24, 26-27, 31-38, 48-49, and 80-81 are canceled herein without prejudice or disclaimer as drawn to non-elected subject matter. Applicants reserve the right to prosecute the non-elected subject matter in later-filed continuation or divisional applications. Furthermore, Applicants understand that, upon allowance of a generic claim they will be entitled to claim additional non-elected species which fully embrace the allowed generic claim.

No new matter is presented in this amendment.

### Traversal of Supplemental Restriction and Provisional Election of Insulin

In response to the supplemental requirement for restriction to a single effector, Applicants provisionally elect insulin with traverse. Claims 10, 11, and 15 as amended are readable thereon.

According to the Examiner the recited impermeable molecules are patentably distinct. *See*, Office Action at page 2, ¶ 2. Applicants submit that the recited agents are members of the same genus ("impermeable bioactive molecules"), and are useful for treating metabolic disorders. For example, glucagon-like peptide-1 (GLP-1), a hormone produced in the intestine, induces insulin secretion in a glucose dependent manner, controls gastric emptying and inhibits food intake as well as glucagon and somatostatin secretion. Thus, GLP-1 can be utilized for the treatment of metabolic disorders such as diabetes. Alpha-melanocyte-stimulating hormone ( $\alpha$ -MSH) has an anti-inflammatory effect in celiac mucosa, the inside lining of the intestinal tract that absorbs food into the body, and is also a central regulator of energy homeostasis and appetite through the melanocortin pathway. Thus,  $\alpha$ -MSH can be utilized for the treatment of metabolic disorders such as obesity and Metabolic Syndrome. Parathyroid hormone is the most important endocrine regulator of calcium and phosphorus concentration in extracellular fluid, and is utilized for the treatment of such disorders. Growth hormone, also known as somatotropin, is a protein hormone of about 190 amino acids that is synthesized and secreted by cells called somatotrophs in the anterior pituitary. It is a major participant in control of several complex physiologic processes, including growth and metabolism, including metabolism of lipids and cholesterol. Calcitonin plays a role in calcium and phosphorus

and phosphorus metabolism, and is utilized for the treatment of such disorders. In particular, calcitonin has the ability to decrease blood calcium levels at least in part by effects on bone and kidney.

The specification clearly contemplates delivery of combinations of effectors depending upon what effect is desired. *See*, specification at page 20, lines 6-9. Accordingly, Applicants clearly regard more than one of these bioactive molecules as part of the present invention, as described and claimed. Reconsideration and withdrawal of the restriction requirement is respectfully requested.

#### Species Election for Counter Ion

In response to the requirement for election of a single disclosed species of counter ion, Applicants elect a cationic amphipathic molecule as it relates to a benzalkonium derivative, without traverse. Claims 25, and 28-30 as amended are readable thereon.

#### Species Election for Hydrophobic Carrier

In response to the requirement for election of a single disclosed species of hydrophobic carrier, Applicants elect an aliphatic molecule as it relates to fatty acids, without traverse. Claims 46 and 47 as amended are readable thereon.

#### Traversal of Species Election for Protective Agents and Provisional Election of Aprotinin

In response to the requirement for election of a single disclosed species of protective agents, Applicants provisionally elect aprotinin with traverse. Claims 50, 51, and 82 as amended are readable thereon.

According to the Examiner, the recited protective agents are patentably distinct. *See*, Office Action at page 3, ¶ 5. Applicants submit that the recited agents are members of the same genus ("protease inhibitors"), and are so closely related that a search of the entire claim as amended can be made without serious burden to the Examiner. *See*, MPEP § 803.02. Specifically, aprotinin and Bowman-Birk Inhibitor are serine protease inhibitors. Additionally, Bowman-Birk Inhibitor is derived from soybeans, as is soybean trypsin inhibitor. Accordingly, Applicants have amended the claims to recite these protective agents. Reconsideration and withdrawal of the species election is requested.

Traversal of Species Election for Additional Substances and Provisional Election of Non-ionic Detergent

In response to the requirement for election of a single disclosed species of additional substances, Applicants provisionally elect a non-ionic detergent with traverse. Claims 77-79, and 82-83 as amended are readable thereon.

According to the Examiner, claim 77 is generic. *See*, Office Action at page 4, ¶ 3. Applicants disagree. Notwithstanding, Applicants submit that a search of the entire claim as amended can be made without serious burden to the Examiner. *See*, MPEP § 803.02. Specifically, claim 42 already recites a poloxamer and Solutol HS15, and claim 51 already recites a protease inhibitor. Thus, the only additional substance recited by amended claim 77 that the Examiner would have to search is a reducing agent.

Additionally, it is improper for the Patent Office to refuse to examine that which Applicants regard as their invention. *See*, MPEP § 803.02 (citing *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978); *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Claim 77 recites a composition further comprising a mixture of at least two of the substances recited therein. Moreover, the specification is replete with examples that teach the use of a combination of these substances. *See*, specification Tables 3-5, and 7-8.

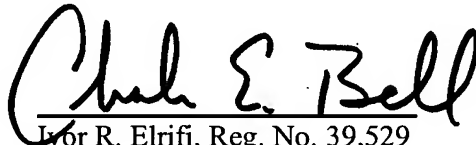
Accordingly, Applicants clearly regard more than one of these substances as part of the invention, as described and claimed. Reconsideration and withdrawal of the species election requirement is respectfully requested.

**Conclusion**

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. Should any questions or issues arise concerning this application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

A Petition for a Two-Month Extension of Time and the required fee are filed herewith. With the extension, this response is due on or before August 18, 2005. Applicants believe no additional fees are due with this response. The Commissioner is hereby authorized to charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 24348-501 CIP.

Respectfully submitted,



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